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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,522	04/05/2001	John R. DePhillipo	E0543-00002	2835

8933 7590 09/01/2004

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,522

Applicant(s)

DEPHILLIPO ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 98-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2004 has been entered.

Status of the Application

2. Claims 98-104 are pending and have been subjected to the restriction requirement below.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-18, Claim 98 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing occurrence in the human's genome of disorder-associated polymorphisms selected from the group consisting of polymorphisms a)-r). Therefore, if Applicants wish to elect the polymorphism of a), then Applicants would elect Group 1; if Applicants wish to elect the polymorphism of b), then Applicants would elect Group 2, etc.

Groups 19-22, Claims 98-99 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing polymorphisms e), f), at least one of a) and b), and at least one of c) and d). Therefore, if Applicants wish to elect the polymorphism combination of e), f), a) and c), then Applicants

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would elect Group 19; if Applicants wish to elect the polymorphism combination of e), f), a) and d), then Applicants would elect Group 20, etc.

Group 23, Claims 98 (in part) and 100, drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing each of disorder-associated polymorphisms a) through f).

Groups 24-3,083, Claims 98 (in part) and 101 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing at least four of a) through r). Therefore, if Applicants wish to elect the polymorphism combination of a), b), c) and d), then Applicants would elect Group 24; if Applicants wish to elect the polymorphism combination of a), b), c) and e), then Applicants would elect Group 25, etc.

Groups 3,084-21,647, Claims 98 (in part) and 102 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing at least six of a) through r). Therefore, if Applicants wish to elect the polymorphism combination of a), b), c), d), e), and f) then Applicants would elect Group 3084; if Applicants wish to elect the polymorphism combination of a), b), c), d), e), and g), then Applicants would elect Group 3085, etc.

Groups 21,648-65,405, Claims 98 (in part) and 103 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing at least ten of a) through r). Therefore, if Applicants wish to elect the polymorphism combination of a), b), c), d), e), f), g), h), i), and j), then Applicants would elect

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Group 21648; if Applicants wish to elect the polymorphism combination of a), b), c), d), e), f), g), h), i), and k), then Applicants would elect Group 21649, etc.

Groups 65,406-66,221, Claims 98 (in part) and 103 (in part), drawn to a method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing at least ten of a) through r). Therefore, if Applicants wish to elect the polymorphism combination of a), b), c), d), e), f), g), h), i), j), k), l), m), n), and o) then Applicants would elect Group 65406; if Applicants wish to elect the polymorphism combination of a), b), c), d), e), f), g), h), i), j), k), l), m), n), and p), then Applicants would elect Group 65407, etc.

4. Groups 1-66,221 are drawn to claims that recites a single polymorphism, and claims that recite multiple combinations of polymorphisms. Each nucleic acid sequence and polypeptide comprising a polymorphism is patentably distinct from each other because they each differ in structure and function. Nucleotide sequences with single nucleic acid changes and polypeptides with single amino acid changes are structurally distinct chemical compounds and have different functions. Accordingly, if Applicant wishes to elect one of Groups 1-18, Applicant must elect a single polymorphism.

Furthermore, each combination of polymorphisms are separate and distinct from one another because they drawn to detecting combinations of nucleic acids (or polypeptides) that are structurally and functionally distinct. Moreover, the search and examination of all possible combinations would pose an enormous burden on the examiner and on the USPTO search resources. Therefore, if applicant wishes to elect a method comprising assessing occurrence in the human's genome of disorder-associated polymorphisms comprising a combination of polymorphisms, Applicant is required to elect a specific combination of polymorphisms (e.g., a specific Group from Groups 19-66,221).

The nucleic acid sequences and polypeptides are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. This is NOT an election of species. Absent evidence to the contrary, each such nucleotide sequence (or polypeptide) are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted.” 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Accordingly, Applicant is required to elect a **single** patentably distinct polymorphism or a **single** combination of polymorphisms as stated above.

5. Because each nucleic acid sequence and polypeptide are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their recognized divergent subject matter and because each nucleic acid sequence and polypeptide require different searches that are not co-extensive, examination of these distinct compounds would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

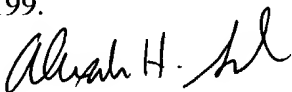
If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Alexander H. Spiegler
August 26, 2004



CARLA J. MYERS
PRIMARY EXAMINER